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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,540	02/08/2002	James Arthur Hoffmann	X-11368A	4243
25885	7590	01/11/2005	EXAMINER	
ELI LILLY AND COMPANY PATENT DIVISION P.O. BOX 6288 INDIANAPOLIS, IN 46206-6288			DELACROIX MUIRHEI, CYBILLE	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,540	HOFFMANN, JAMES ARTHUR	
	Examiner Cybille Delacroix-Muirheid	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 September 2004 and 14 October 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 35-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 35-54 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

Detailed Action

1. Claims 35-53 and (54) are rejected under 35 U.S.C. 103(a) as being unpatentable over Knudsen et al., 6,458,924.
2. Claims 35-53 and (54) are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,358,924 in view of Knudsen et al., *supra*.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New claim 54 falls under the claim rejections under 35 USC 103(a) and the judicially created doctrine of obviousness-type double patenting for reasons given previously in the office action mailed June 18, 2004. Further comments with respect to this claim will be made below.

Response to Amendment(s)

The following is responsive to Applicant's amendment and remarks received Sep. 17, 2004 and Oct. 14, 2004.

Claims 1-34 are cancelled. New claim 54 is added. Claims 35-54 are currently pending.

The previous claim objection(s) set forth in paragraph 1 of the office action mailed June 18, 2004 is withdrawn in view of Applicant's amendment and the remarks contained therein.

The previous rejection of claim 53 under 35 USC 112, first paragraph, set forth in paragraph 2 of the office action mailed June 18, 2004 is withdrawn in view of Applicant's amendment and the remarks contained therein.

However, Applicant's arguments traversing (1) the previous claim rejection under 35 USC 103(a) and (2) the previous claim rejection under obviousness-type double patenting, set forth in paragraphs 3-4 of the office action mailed June 18, 2004 have been considered but are not found to be persuasive.

Said rejections are maintained essentially for the reasons given previously in the office action mailed June 18, 2004 with the following additional comment:

Applicant essentially argues that the Knudsen et al. reference is not prior art and that both the obviousness rejection and the double patenting rejections are moot. More specifically, Applicant states,

"Knudsen et al (US 2001/0011071) is cited as art of interest. However, Knudsen et al's disclosure of specific surfactants (see, e.g., paragraph 1605) is not supported in the disclosure of Knudsen et al's priority applications serial no. 08/918,810 or PCT/DK97/00340 (= WO Patent Application 98/08871), and accordingly Knudsen et al is not prior art against the instant claims (See Notice of Allowability, paper number 16 of 09/585,181 dated Oct. 20, 2001.)"

Said arguments have been considered but are not found to be persuasive.

The Examiner respectfully submits that the Knudsen et al. reference (US 2001/0011071) cited of interest but determined not to be prior art against the claims of parent application 09/585,181 is not the reference relied upon in the rejections submitted in this application. The reference used in the claim rejections under 35 USC 103(a) and under obviousness-type double patenting is Knudsen et al. 6,458,924, which has priority back to Jan. 24, 1997, the filing date of provisional application numbers

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60/035,904 and 60/036,255. Therefore Knudsen et al., '924 remains available as prior art under 35 USC 102(e). The previous rejection under 35 USC 103(a) and the previous double patenting rejection are maintained.

New claim 54 falls under the rejection under 35 USC 103(a) since Knudsen et al. teach that the GLP-1 derivatives may be used in the treatment of non-insulin dependent diabetes mellitus also known as Type II diabetes. Please see col. 156, lines 43-46.

Conclusion

Claims 35-54 stand rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number

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is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM CM
Jan. 7, 2005

Christopher Low
Supervisory Patent Examiner
Zahra Fazal